

REMARKS

The Office action of August 18, 2008, has been carefully considered.

Claims 16-20 have been rejected under 35 USC 103(a) over Cooper et al and Chantler et al.

Cooper et al is cited as teaching a method for treating mammalian spermatozoa with amphipathic amines in order to induce loss of fertility. The composition disclosed includes a cycloalkyl amine incorporated into a hydroxyethyl cellulose gel to form compositions containing 5 to 10% by weight of cyclohexylamine hydrochloride.

In the second paragraph of page 7 of the Office action, it is stated that "Cooper et al. teach a non-toxic topical contraceptive composition which exhibits a high contraceptive activity without being irritating to the vaginal mucosa (column 1, lines 55-58)." While this is stated as being an object of the invention, Applicant disputes the seeming allegation in the Office action that this object has been achieved by the disclosed compositions, especially since no evidence has been introduced by Cooper et al that the compositions are non-irritating, and more especially in light of the knowledge of the art that compositions containing nonoxynol 9 (see example 2B and 2C in col 9) can be irritating.

The rejection appears to be based upon the statement at the bottom of page 8 of the Office action that "Cooper et al teach additional adjuvants, which may be incorporated into these formulations, such as antiseptic agents (column 9, line 61)."

With reference to column 9, Cooper et al teaches that the compositions may contain additional adjuvants including emulsifying agents, propelling agents, microscopic agents, buffers, anti-molding agents, antiseptic agents, antioxidants and perfumes. The sole antiseptic agents identified are boric acid, cresols, chlorinated phenols and organomercuric salts. Methylparaben or propylparaben are in the list of additional

adjuvants, but they are only identified as being anti-molding agents.

Chantler et al has been cited as teaching contraceptive products containing chlorhexidine, and it is alleged that it would have been *prima facie* obvious to combine the teachings of Cooper et al and Chantler et al "which are alleged to teach the central objective of the instant claimed invention which are both drawn to contraceptive products."

Applicant recognizes that a composition arrived at from a combination of Cooper et al and Chantler et al could well be within the level of ordinary skill in the art, since both references are directed to contraceptive products. However, the result of such a combination of references would be a contraceptive jelly composition containing chlorhexidine and including an anti-molding agent which might be methylparaben or propylparaben.

The Examiner is reminded, however, that the claimed invention is not directed to a composition, but to a method, and Applicant submits that this method is nowhere disclosed in either of the cited references.

Applicant recognizes that it is generally known in the art to apply a composition containing a lubricant and an effective amount of a spermicidal agent. Applicant has discovered that such application results in destruction of the normal flora of the vagina, resulting in fungal infections which cause the composition to be highly irritating. That is why the composition of Cooper et al, with "high contraceptive activity" would also be expected to be highly irritating.

In order to prevent such fungal infections and the resultant irritation, Applicant teaches the inclusion in the composition of "an effective amount of a fungicide to prevent the growth of fungi in the vagina which grow in the absence of natural bacterial flora destroyed by the antiseptic." Such a step is not disclosed or suggested in the prior art.

The use of anti-molding agents in pharmaceutical

compositions is clearly well known. However, the parabens in Cooper et al are listed only as anti-molding agents, and their function as such is to prevent the composition from deteriorating during storage. The concentration of anti-molding agents in lubricating and gel formulations is generally small, and these materials have not, prior to the claimed invention, been recognized as an active ingredient to supplement the activity of the spermicidal antiseptic active agents during the use of the formulation.

Neither of the cited references discloses or suggests a method of using fungicides as active ingredients serving the utility of the formulation, preventing fungal infections which result from the use of the spermicide. Claim 16 of the application specifically defines the quantity of the fungicide as the amount effective to prevent the growth of fungi *in the vagina*, and this amount is not identical to the amount incorporated as an anti-molding or preservative material.

Thus, while the Cooper et al reference as well as the general state of the art may make it obvious to incorporate anti-molding agents into spermicidal compositions, the cited references do not as a whole teach a step of incorporating fungicide into a spermicidal composition in order to prevent the growth of fungi in the vagina. For this reason, the invention as claimed is not obvious over the art of record, and withdrawal of this rejection is requested.

With regard to the double patenting rejection, Applicant once again requests that this rejection be held in abeyance until otherwise patentable subject matter is agreed upon.

In view of the foregoing remarks, Applicant submits that the present application is now in condition for allowance. An early allowance of the application is earnestly solicited.

Respectfully submitted,

  
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